

## REMARKS

### A. Status of the Claims

Claims 1-88 are pending in the present application. The Office Action dated September 23, 2003 rejected claims 1-3, 7-15 and 86-88. Claims 1-3, 7-15 and 86-88 are rejected under 35 U.S.C. §112, first paragraph and second paragraph. Claims 1 and 86 are rejected under 35 U.S.C. 102(b) under Prasad *et al.* The specific grounds for the rejections, and Applicants' responses thereto, are provided herein.

Applicants have amended claims 1 and 7. Support for the amendments may be found in the claims as originally filed and on pages 6-13, page 20 lines 6-7, pages 22-27 and pages 78-79 of the specification. Thus, no new matter has been added. Therefore, claims 1-3, 7-15 and 86-88 are presented for reconsideration.

### B. Rejection of the Claims Under 35 U.S.C. §112, Second Paragraph is Overcome

The Action rejects claims 1-3, 7-15 and 86-88 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, the Action contends that recitation of the term "HN-1" is considered a laboratory term and is therefore considered indefinite because there are other proteins which are also recognized by the same name. Claims 1 and 7 have been amended to more clearly define the invention.

Claims 1 and 7 as amended herein each specify that the HN-1 peptide, variant HN-1 peptide, or HN-1 related peptide comprise SEQ ID NO:1, disclosed in the instant specification. Support for amendment to claims 1 and 7 may be found on page 20, lines 6-7 of the specification and in Example 2 on pages 78-79, specifically, on pages 79, lines 8-10.

Therefore, in light of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 1-3, 7-15 and 86-88 under 35 U.S.C. §112, second paragraph as being indefinite.

**C. Rejection of the Claims Under 35 U.S.C. §112, First Paragraph – Written Description is Overcome**

The Action rejects claims 1-3, 7-15 and 86-88 under 35 U.S.C. §112, first paragraph as lacking written description. The Action contends that the claims recite "a variant of HN-1 or a HN-1 related peptide" as part of the invention, however, there does not appear to be an adequate written description in the specification as filed of the essential structural feature that provides the recited function of targeting tumors. The Action also contends that Applicants do not appear to have reduced to practice any variant of HN-1 or any HN-1 related peptides. The Action further contends that Applicants have not provided sufficient written description of any structure that may be correlated with the desired targeting function. The Action states that a "HN-1 variant or related peptide" encompasses *any* molecule with the functional activity of targeting a tumor.

Applicants traverse the rejection, but direct the Examiner to the amended claims, claims 1 and 7. As discussed above, the claimed peptides now all reference SEQ ID NO:1. In light of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph.

**D. Rejection of the Claims Under 35 U.S.C. §112, First Paragraph – Enablement is Overcome**

Claims 1-3, 7-15, and 86-88 are rejected under 35 U.S.C. § 112, first paragraph, because the Action alleges that the specification, while being enabling for a peptide that is SEQ ID NO:1, does not reasonably provide enablement for variants or related peptides of SEQ. ID. NO:1.

Applicants traverse the rejection, but direct the Examiner to claims 1 and 7, which have been amended to include "SEQ ID NO:1" therefore more distinctly claiming the invention. In light of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

**E. Rejection of the Claims Under 35 U.S.C. §102(b) is Overcome**

Claims 1 and 86 are rejected under 35 U.S.C. § 102 (b), as being anticipated by Prasad *et al.* The Action contends that Prasad *et al.*, teach a peptide termed HN-1. The Action further states that although Prasad *et al.* do not specifically characterize the peptide as being able to internalize into a tumor, the claims are drawn to the product *per se* and inherently, such a polypeptide would be able to internalize into a tumor cell. Applicants traverse the rejection.

As discussed previously, the HN protein of Prasad *et al.* is in no way related to the HN-1 peptide claimed here. However, to more clearly distinguish the claimed invention from the cited art, Applicants have amended claim 1 to recite the amino acid sequence of SEQ ID NO:1. Thus, the HN-1 peptide as now claimed is clearly distinguished from that described by Prasad *et al.* In light of the foregoing, Applicant respectfully request that the Examiner reconsider and withdraw the rejection.

**F. Conclusion**

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejection of all claims be withdrawn so they may pass to issuance.

The Examiner is invited to contact the undersigned agent at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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